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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,604	02/08/2002	Felix Franks	0022.11	2751

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INHALE THERAPEUTIC SYSTEMS, INC
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EXAMINER

COE, SUSAN D

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 09/26/2002

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

10/072,604

Applicant(s)

FRANKS ET AL.

Examiner

Susan Coe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 07/902,838.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____

DETAILED ACTION

1. Claims 1-14 are currently pending.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 5,928,469. Although the conflicting claims are not identical, they are not patentably distinct from each other because there is significant overlap in scope between the claimed invention and the patented claims. The claims of US '469 are drawn to a process for storing biological materials by spray drying the material in the presence of a carrier that becomes forms a glassy material. The claims of US '469 are of a slightly narrower scope that is encompassed by the broader scope of the current claims. Therefore, the conflicting scope of the claims shows that the present claims are not patentable over the pending claims.

3. Claims 1-14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over all the claims of U.S. Patent No. 6,071,428. Although the

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conflicting claims are not identical, they are not patentably distinct from each other because the claims of US '428 teach a process for making a storage stable composition that contains a glassy carbohydrate substance and a biologically active material. The process can include spray drying (see claim 10). Therefore, while the claims of US '428 are not identical to the present claims, a person of ordinary skill in the art would reasonably expect that the invention claimed in US '428 could be modified to create the same invention as claimed in the current application because the claims of US '428 clearly teach process for making a storable, glassy, spray dried composition containing the same ingredients as currently claimed.

4. Applicant is advised that should claim 4 be found allowable, claim 6 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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5. Claims 1-7, 10, 11, 13, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by van de Beek et al. (Neth. Milk Dairy Journal (1969) Vol. 23, pp. 46-54) in light of Roos Carbohydrate Research, (1993) vol. 238, pp. 39-48) and European Patent Application No. 0 383 569, as evidence of inherency.

The claims are drawn to a method of storing materials by spray drying particles of a biological material and a carrier substance that exists in a glassy state. The spray dried particles form glassy particles.

Van de Beek teaches a method of preserving enzymes by spray drying the enzyme rennin in the presence of sucrose and lactose. The sucrose was present in a percentage of 2% to 20%, and the lactose was present at a concentration of 5% or 10% (see Table 1, page 49). The spray dried compositions of rennin and sucrose and rennin and lactose were stored at room temperature for 250 days and did not display any loss of biological material (see page 49). Van de Beek does not discuss if the spray dried composition are able to exist in a glassy state; however, sucrose and lactose alone are able to exist in a glassy state with glass transition temperatures of 62°C and 101°C, respectively (see Roos, Table I, page 41). Van de Beek does not teach that the spray-dried compositions of sucrose and rennin and lactose and rennin exist in a glassy state.

However, since van de Beek's spray-dried compositions of rennin and sucrose and rennin and lactose are created in the same manner as claimed by applicant, van de Beek's spray-dried compositions would inherently be in a glassy state if applicant's invention functions as claimed.

In addition, EP '569 also states that mixing an organic substance with a glass forming substance lowers the glass transition temperature of the glassy substance 5°C (see page 4, lines

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30-31). Thus, the spray dried particles of rennin and sucrose and rennin and lactose taught by van de Beek would inherently have a glass transition temperature above 50°C.

6. Claims 1-4, 6, 8-11, 13 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Prajapati et al. (Australian Journal of Dairy Technology (March/June 1987), pp. 17-21).

Prajapati teaches spray drying *Lactobacillus acidophilus* with a carrier that contains sucrose. The sucrose can be present at 10% or 14% (see Table 1, page 18). Prajapati does not teach that this spray dried composition exists in a glassy state; however, as stated above, sucrose is able to exist in a glass state by itself and the composition would inherently form a glassy composition because the steps followed by Prajapati are the same as those claimed.

7. Claims 1-7, 10, 11, 13, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Okura Seiyaku (Abstract - Japanese Patents Gazette - Week 8604 - Section Chemical - J6 0244-288 A (1988)) (referred hereafter as “Okura”).

Okura teaches preparing a stable serrapeptidase powder by spray drying the serrapeptidase with up to 25% lactose. This composition is considered to inherently be in a glassy state for the reasons stated above. Okura states that the activity of the serrapeptidase is not lost after long storage periods.

8. Claims 1-7 and 10-14 are rejected under 35 U.S.C. 102(b) as being anticipated by 3,202,731 in light of Klech et al. (Journal of Pharmaceutical Sciences (1990), Vol. 79, pp. 999-1004), as evidence of inherency.

US ‘731 teaches preserving proteins by spray drying them in the presence of carbohydrates and gelatin. The carbohydrates and gelatin are present at 20 to 40% (see column 2, lines 56 and 57, column 3, lines 13-25 and claim 4). Completely dehydrated gelatin has a

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glass transition temperature of 120°C to 200°C (see Klech, page 1001 last paragraph). This composition is considered to inherently be in a glassy state for the reasons discussed above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-11 and 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over European Pat. No 0 383 569 in view of van de Beek et al.

EP '569 discloses a storage stable composition with an active material selected from proteins, peptides, nucleosides, nucleotides, dinucleotides, oligonucleotides, or other materials from a natural source (see page 3, lines 20-32) and a carrier substance that is able to form a glass, such as a carbohydrate. Four of the suggested carriers are glucose, maltose, maltotriose, and sucrose. The substances have glass transition temperatures of 31, 43, 76, and 55°C, respectively. The mixture of the active substance and the carrier has a glass transition temperature that is 5° below the glass transition temperature of the carrier substance (see page 4, lines 30-end).

While EP '569 teaches a composition with the same components as the claimed invention, EP '569 does not teach spray drying the composition. Van de Beek does disclose spray drying as a method of preserving biological materials. Van de Beek teaches that spray drying sugars and proteins together is a very successful means of preserving the activity of the

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protein. This reference also teaches spray drying with a sugar concentration of 20%. Van de Beek shows that the use of spray drying to preserve composition of sugars and proteins was known in the art at the time of the invention. A person of ordinary skill in the art would have had a reasonable expectation that spray drying as taught by van de Beek would have been a successful means of further stabilizing the storage compositions of sugars and biological materials taught by EP '569. Therefore, the artisan of ordinary skill would have been motivated to preserve the compositions taught by EP '569 using the spray drying technique taught by van de Beek.

10. Claims 1 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP '569 in view of van de Beek and US Pat. No. 3,617,302 in light of Klech et al. (Journal of Pharmaceutical Sciences (1990), Vol. 79, pp. 999-1004).

As discussed above, the combination of EP '569 and van de Beek teach spray drying carbohydrates and biological materials to render the biological materials stable. However, these references do not teach using a protein as the carrier substance for the biological material. US '302 teaches that any protein, specifically gelatin, can be used as a spray dried carrier for biological lipids (see column 1, last paragraph and column 2, lines 1-14). Completely dehydrated gelatin has a glass transition temperature of 120°C to 200°C (see Klech, page 1001 last paragraph).

US '302 shows that the use of gelatin as a spray dried carrier was known in the art at the time of the invention. Based on this disclosure, a person of ordinary skill in the art would have expected that gelatin would function as a suitable carrier for the biological materials taught by EP '569. Therefore, a person of ordinary skill in the art would have been motivated to substitute

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the carbohydrate carriers taught by EP '569 for the gelatin carrier taught by US '302 for use in spray drying.

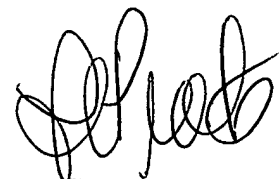
10. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (703) 306-5823. The examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SDC
September 23, 2002



FRANCISCO PRATS
PRIMARY EXAMINER